

**IN THE UNITED STATES DISTRICT COURT FOR THE  
NORTHERN DISTRICT OF GEORGIA**

**JULIE TUTTLE, individually and** :  
**on behalf of the ESTATE OF** :  
**MICHAEL PAUL TUTTLE, et al.,** : **CASE NO. 1:20-cv-04744**  
: **JUDGE LEIGH MARTIN MAY**  
**Plaintiff,** :  
**V.** :  
**DEXCOM, INC.,** :  
**Defendant.** :

# **FIRST AMENDED COMPLAINT**

Plaintiff Julie Tuttle files this First Amended Complaint against Defendant Dexcom, Inc. seeking damages for the failure of Dexcom's G6 glucose monitoring system and alleges as follows:

## JURISDICTION AND VENUE

1.

Julie Tuttle is a citizen and resident of the State of Georgia. Plaintiff was the wife of Michael Tuttle and is the legal next-of-kin and administrator of the Estate of Michael Paul Tuttle. As such, she is the proper party to bring this action.

2.

Defendant Dexcom, Inc. is a Delaware Corporation with its principal place

of business located at 6340 Sequence Drive, San Diego, California, 92121. Defendant Dexcom may be served with process by serving its registered agent Corporation Service Company at 40 Technology Parkway South, Suite 300, Norcross, Gwinnett County, Georgia 30092.

3.

Plaintiff originally filed this lawsuit in Gwinnett County Superior Court, which is inside the Northern District of Georgia.

4.

Plaintiff served Defendant with this lawsuit at some time between October 23, 2020 and October 27, 2020.

5.

Dexcom timely filed a notice of removal on November 20, 2020 on a diversity basis, pursuant to 28 U.S.C. §§ 1332, 1441, 1446, and all applicable laws, which Plaintiff did not oppose.

6.

As such, venue and jurisdiction are proper.

### **THE G6 SYSTEM**

7.

Dexcom designs, develops, manufactures, promotes, supplies, distributes,

sells, and instructs in the use of the Dexcom G6 Continuous Glucose Monitoring System (“G6 System”).

8.

The G6 System is intended for use by diabetics to replace fingerstick blood glucose testing for diabetes treatment decisions. See User Guide, 20 (attached as Exhibit A).

9.

According to Dexcom, “The Dexcom G6 CGM System stands out as the first real-time, integrated CGM (iCGM) requiring zero fingersticks or calibrations” unless a user’s “symptoms or expectations do not match readings.”

<https://www.dexcom.com/faqs/does-the-dexcom-g6-cgm-system-require-calibrations>.

10.

Dexcom also markets that the G6 System aids users in the detection of hyperglycemia and hypoglycemia by alerting users to these events, facilitating both acute and long-term therapy adjustments. User Guide, 20.

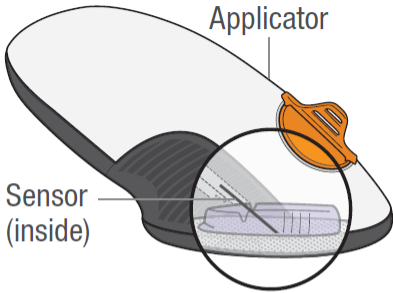
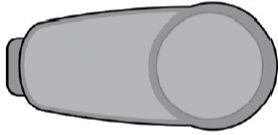

11.

Dexcom included the User Guide for the G6 System contemporaneously with the sale and as part of the sale of the G6 System. See Dexcom’s Supporting

Brief, 8.

12.

The G6 System has three key parts: 1) the sensor that collects glucose information, 2) the transmitter that sends the glucose information from the sensor to the display device, and 3) the display device that shows the glucose information to the user, as demonstrated in the G6 System User Guide:

What you see	What it's called	What it does
	Applicator with built-in sensor	<p>Applicator helps you insert the sensor wire under your skin.</p> <p>Sensor gets your glucose information.</p>
	Transmitter	Transmitter sends your glucose information from the sensor to the display device.
	<p>Display Device(s):</p> <ul style="list-style-type: none"> <li>• Receiver</li> <li>• Your smart device</li> </ul>	<p>Display device(s) shows your glucose information.</p> <p>Receiver is required for Medicare.</p>

13.

Dexcom designs, develops, manufactures, promotes, supplies, distributes,

sells, and instructs in the use of the sensor for the G6 System.

14.

Dexcom designs, develops, manufactures, promotes, supplies, distributes, sells, and instructs in the use of the transmitter for the G6 System.

15.

Dexcom designs, develops, manufactures, promotes, supplies, distributes, sells, and instructs in the use of the Dexcom G6 application for iPhones (“G6 App”).<sup>1</sup> The G6 App allows the user to use their iPhone as the display device when using the G6 System.

16.

Failure to receive glucose information can result in injury or death of a diabetic.

17.

Failure to recognize an occurrence of hyperglycemia or hypoglycemia in a diabetic can result in injury or death.

18.

The G6 System is only available to users by prescription.

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<sup>1</sup> See <https://apps.apple.com/us/app/dexcom-g6/id1209262925>.

19.

According to the Manufacturer and User Facility Device Experience database (“MAUDE”) run by the United States Food and Drug Administration (“FDA”), thousands of users have notified Dexcom that the alarms in its predecessor models, the G5 and G4 Platinum CGM, are unreliable and inadequate.

20.

In numerous cases, users have reported that the sensors, transmitters and/or display devices on the G6 System and its predecessors fail to work. For example on May 7, 2019, the day Michael Tuttle was prescribed the G6 System, MAUDE shows that Dexcom received (and later confirmed) user reports that a sensor failed prematurely, a transmitter failed, and a loss of connection occurred.

21.

Numerous users have warned Dexcom that the G6 System and its predecessors will often not sound during severe hyperglycemic and hypoglycemic events. For example, MAUDE shows that on May 7, 2019, Dexcom also received a report that a patient’s blood sugar became dangerously low when the G6 failed to provide an alert.

[https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI\\_ID=8588348&pc=QBJ](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=8588348&pc=QBJ)

22.

Numerous users have warned Dexcom that the G6 System's predecessors will test properly but then fail to sound when users are experiencing dangerously high or low glucose levels. The G6 is designed to (and marketed as having the ability to) self-test (self-calibrate), but users have warned Dexcom that the G6 System will fail to sound when users are actually experiencing dangerously high or low glucose levels after the self-calibration. Some of these users have died. For example, see:

[https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI\\_ID=8582725&pc=QBJ](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=8582725&pc=QBJ)

### **FDA CLASSIFICATION AND REVIEW OF MEDICAL DEVICES**

23.

The Food and Drug Administration (FDA) has established classifications for approximately 1,700 different generic types of devices.

<https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device>.

24.

Each generic type of device is assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the

device. <https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device>.

25.

The three classes and the requirements which apply to them are:

Class I – General Controls;

Class II - General Controls and Special Controls; and

Class III - General Controls and Premarket Approval.

<https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device>.

26.

All classes of devices are subject to General Controls. General Controls are the baseline requirements of the Food, Drug and Cosmetic (FD&C) Act that apply to all medical devices, Class I, II, and III. <https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device>.

27.

The class to which a device is assigned determines, among other things, the type of premarketing submission/application required for FDA clearance to market. <https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device>.

28.

If a device is classified as Class I or II, and if it is not exempt, a 510k is required for marketing. <https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device>.

29.

Due to the level of risk associated with Class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of Class III devices. <https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma>.

30.

For Class III devices, a premarket approval application (PMA) is required for marketing unless the device fits an exception. <https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device>.

31.

PMA is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices.

<https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma>

32.

Once a device has received PMA, the MDA forbids the manufacturer to make, without FDA permission and approval, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness. 21 USCS § 360e(d)(6)(A)(i); [Riegel v. Medtronic, Inc., 552 U.S. 312, 319, 128 S. Ct. 999, 1005, 169 L.Ed.2d 892, 900 \(2008\).](#)

33.

Even after approval, PMA devices remain subject to reporting requirements. [Riegel v. Medtronic, Inc., 552 U.S. 312, 319, 128 S. Ct. 999, 1005, 169 L.Ed.2d 892, 900 \(2008\).](#)

34.

“PMA is the most stringent type of device marketing application required by FDA,” and “PMA requirements apply to Class III devices, the most stringent regulatory category for medical devices.” [https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma.](https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma)

35.

A manufacturer of a medical device can avoid PMA if it requests a 510(k) review and the FDA determines the device is "substantially equivalent" to another device exempt from PMA. 21 USCS § 360c(f)(1)(A).

36.

Initial 510(k) review allows the FDA to determine whether the device is equivalent to a device already placed into one of the three classification categories.

<https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances>.

37.

If a medical device manufacturer is granted substantial equivalence under the 510(k) review, it is required to submit another 510(k) when the device is significantly changed or modified to the extent that its safety or effectiveness could be affected.

38.

Devices granted 510(k) status are not required to undergo PMA.

39.

Devices that were not available on the market before the passage of the Medical Device Amendments of 1976 are automatically classified into Class III, regardless of the risk they pose. <https://www.fda.gov/about-fda/cdrh-transparency/overview-medical-device-classification-and-reclassification>.

40.

However, even if there is not already a substantially equivalent device, a medical device manufacture can avoid automatic classification as a Class III device if it requests and is granted De Novo Classification (“DNC”) as a Class I or Class II device by the FDA. 21 USCS § 360c(f)(1)(C).

41.

Devices granted Class II classification under De Novo Classification are not subject to PMA.

42.

After having a request for De Novo classification as a Class II device granted, a manufacturer does not have to supplement his application to change aspects of the device but can instead submit 510(k) notice to the FDA.

### **FDA CLASSIFICATION AND REVIEW OF THE G6 SYSTEM**

43.

On or about December 7, 2017, Dexcom requested De Novo classification for the G6 System.

44.

On or about March 27, 2018, the FDA granted Dexcom’s request and classified the generic device type of the Dexcom G6 System as an Integrated

continuous glucose monitoring system, factory calibrated (“ICGM System”).)

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?ID=DEN170088>.

45.

ICGM Systems are Class II devices, therefore, the G6 System is a Class II device.

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/classification.cfm?id=682>.

46.

The FDA published two documents in connection with granting Dexcom’s request, a Reclassification Order and a Decision Summary. Exhibits B and C.

47.

The Reclassification Order and Decision Summary both indicate that the FDA classified the G6 System as a Class II device. Id.

48.

“The performance characteristics of the G6 [System]...conform to the guidance for devices in the same classification.” User Guide, 291.

49.

In the FDA's review, "Accuracy of the Dexcom G6 System was evaluated by comparing iCGM values obtained at the same or similar time points to the comparator methods." Exhibit C.

50.

Dexcom's User Guide gave more specifics about the device that served as the comparator for FDA review.

51.

"While using the G6 in the clinic, subjects had their blood glucose measured every 15 minutes with a laboratory reference method, the Yellow Springs Instrument 2300 STAT Plus™ Glucose Analyzer. This instrument is referred to as the "YSI." Readings from the G6 were reported every 5 minutes and paired with YSI values in order to characterize the accuracy of the G6's glucose reading.... Accuracy of the G6 is characterized by assessing its readings against blood glucose values from YSI. Accuracy of the G6 was assessed with paired G6 readings to YSI blood glucose values." User Guide, 292.

52.

“The ability of the G6 to detect high and low glucose levels is assessed by comparing G6 results to YSI results at low and high blood glucose levels and determining if the alert may have sounded.” User Guide, 306.

53.

The G6 was not required to undergo PMA prior to marketing.

54.

When Dexcom made changes to the G6 System, Dexcom was not required to submit a supplement PMA application. Instead, Dexcom submitted only a 510(k) notification. See Exhibit D.

55.

To date, Dexcom submitted seven 510(k) notifications of changes to the G6 System, including submitting a 510(k) on February 4, 2019. See Exhibit D.

56.

Before November 9, 2019, Dexcom had released at least 8 versions of the G6 App used by Michael Tuttle.

57.

“The G6 [System] isn't compatible with previous generations such as the Dexcom G4 PLATINUM System or the Dexcom G5 Mobile system.” User Guide, 48.

### **DEXCOM'S OTHER GLUCOSE MONITORING SYSTEMS**

58.

Other than the G6 System, the FDA had never classified any of Dexcom's glucose monitoring systems as a generic device type of ICGM. For example, the G4 System was classified as “Sensor, Glucose, Invasive.”

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P120005>.

59.

The G4 System was a Class III device. Other than the G6 System, the FDA had classified all of Dexcom's glucose monitoring systems as Class III devices, the most stringent regulatory category for medical devices. For example, “Sensor, Glucose, Invasive,” the generic device type of the G4 System, was a Class III device. Id.

60.

Other than the G6 System, the FDA required PMA, the most stringent type of device marketing application, for all Dexcom's glucose monitoring systems

prior to marketing. For example, the G4 System was approved by PMA, as indicated in two documents the FDA published in connection with granting Dexcom's request, an Approval Order and a Summary of Safety and Effectiveness. Exhibit E and F. The FDA also published required labeling for the G4 System. Exhibit G.

61.

Other than the G6 System, the FDA has required "Annual Reports" for Dexcom's glucose monitors for continued approval of the PMA. For example, FDA required yearly reports for the G4 System. See Exhibit E.

62.

Other than the G6 System, the FDA required Dexcom to supplement the PMA applications and receive FDA approval before making any changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness. For example, the G4 System has submitted 87 PMA supplements to date.

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P120005>.

63.

Other than the G6 System, the FDA required Dexcom to supplement the PMA applications and receive FDA approval before making any changes to device

firmware and/or software. For example, on August 14, 2013, the FDA approved changes to the G4 System firmware and/or software.

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P120005S005>.

### **MICHAEL TUTTLE'S USE OF THE G6 SYSTEM**

64.

On May 1, 2019, Michael Tuttle's doctor prescribed him the G6 System for the purpose of blood glucose testing, diabetes treatment decisions, and detecting episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments.

65.

Michael purchased the G6 System from Dexcom.

66.

Prior to being prescribed the G6 System, Michael Tuttle had used prior versions of Dexcom's glucose monitoring systems.

67.

During the relevant time, Michael Tuttle used the G6 System for blood glucose testing and for diabetes treatment decisions.

68.

During the relevant time, Michael Tuttle used the G6 System to detect episodes of hyperglycemia and hypoglycemia, facilitating his acute and long-term therapy adjustments.

69.

During the relevant time, Michael Tuttle used the G6 App as the display device for the G6 System.

70.

During the relevant time, Michael Tuttle made no significant changes to the G6 System or G6 App.

71.

During the relevant time, Michael Tuttle treated occurrences of hypoglycemia by taking glucose pills, eating, or drinking to raise his blood sugar level.

72.

On November 9, 2019, Michael Tuttle's G6 App stopped alerting him to hypoglycemia and/or stopped receiving glucose information from the G6 System.

73.

The Daily Report, a report generated by the G6 System, shows that the

failure happened between 10:30 – 11:00 p.m. on November 9, 2019. See Exhibit H.

74.

An audit log generated by the G6 System shows that the last reading happened at 10:37 p.m. on November 9, 2019. See Exhibit I (includes only first and last page).

75.

When Michael Tuttle's G6 App stopped alerting him to hypoglycemia and/or stopped receiving glucose information from the G6 System on November 9, 2019, Michael was using the G6 System as directed by Dexcom.

76.

In the hours after Michael Tuttle's G6 App stopped alerting him to hypoglycemia and/or stopped receiving glucose information from the G6 System, he had a severe occurrence of hypoglycemia (low blood sugar).

77.

Because the Dexcom G6 System failed to alert Michael Tuttle to his hypoglycemia, he was not aware of the hypoglycemia and did not treat the hypoglycemia.

78.

On the morning of November 10, 2019, Michael Tuttle's wife, Plaintiff Julie Tuttle, found Michael unresponsive in bed.

79.

Julie Tuttle called 911.

80.

Emergency medical technicians arrived at the Tuttle home at 8:17 a.m.

81.

Michael Tuttle's blood sugar level was 27 and his Dexcom sensor was on his body.

82.

Michael Tuttle never regained consciousness and was taken to Wellstar North Fulton Hospital for treatment.

83.

On November 19, 2019, Michael Tuttle died of anoxic brain injury and acute respiratory failure due to hypoglycemia.

84.

On that same day, November 19, 2019, Dexcom issued a recall of the same G6 App version used by Michael Tuttle because the G6 App version was not

properly alerting users.

85.

During all relevant times, Michael Tuttle exercised ordinary care for his own safety, and had no opportunity to avoid the consequences of the Dexcom's negligence.

86.

During all relevant times, Michael Tuttle used the G6 System as directed.

**COUNT ONE – STRICT LIABILITY**

87.

Because Dexcom is a manufacturer, as defined by O.C.G.A. § 51-1-11, of the G6 System and G6 App, Dexcom is strictly liable for injuries caused by the G6 being sold without being merchantable and reasonably suited to the use intended.

88.

An injured party may show that the product was “not merchantable” by using three general categories of product defects: manufacturing defects, design defects, and marketing/packaging defects (“failure to warn.”)

89.

The Dexcom G6 System is intended to replace fingerstick blood glucose testing for diabetes treatment decisions.

90.

During the time that Michael Tuttle had his fatal hypoglycemic event, he was using the G6 System according to Dexcom's Recommended Smart Device Settings.

91.

Data from the Dexcom Daily Report and the Dexcom audit logs show the G6 System stopped detecting Michael's glucose levels or providing alerts at approximately 10:37 p.m. on November 9, 2019 and did not resume before Michael's wife found him unresponsive due to his hypoglycemia.

92.

The G6 System had at least the following design defects:

- Failed to prevent clinically significant gaps in sensor data availability that prevented digitally connected devices from achieving their intended use.
- Failed to ensure secure and reliable means of data transmission to provide real-time glucose readings at clinically meaningful time intervals to devices intended to receive the glucose data.
- Failed to ensure that the intended user can use the device safely and obtain the expected glucose measurement accuracy.
- Failed to give a Low alert when the user's glucose level fell below 70 mg/dl.

- Failed to give an Urgent Low Soon alert when the user's glucose level were falling fast and would be 55mg/dl in less than 20 minutes.
- Failed to give an Urgent Low alarm when the user's glucose level fell below 55 mg/dl and failed to repeat the alarm every 30 minutes.
- Failed to give a Sensor Error alert when a sensor error occurred.
- Failed to give a Transmitter Error alert when the transmitter was not working.
- Failed to give a Signal Loss alert when signal was lost.
- Failed to give a No Readings alert when no readings were detected.
- Failed to give a sufficient Sensor Error, Transmitter Error, Signal Loss, or No Readings alert.

93.

The G6 System had at least the following manufacturing defects:

- Failed to prevent clinically significant gaps in sensor data availability that prevented digitally connected devices from achieving their intended use.
- Failed to ensure secure and reliable means of data transmission to provide real-time glucose readings at clinically meaningful time intervals to devices intended to receive the glucose data.

- Failed to ensure that the intended user can use the device safely and obtain the expected glucose measurement accuracy.
- Failed to give a Low alert when the user's glucose level fell below 70 mg/dl.
- Failed to give an Urgent Low Soon alert when the user's glucose level were falling fast and would be 55mg/dl in less than 20 minutes.
- Failed to give an Urgent Low alarm when the user's glucose level fell below 55 mg/dl and to repeat every 30 minutes.
- Failed to give a Sensor Error alert when a sensor error occurred.
- Failed to give a Transmitter Error alert when the transmitter was not working.
- Failed to give a Signal Loss alert when signal was lost.
- Failed to give a No Readings alert when no readings were detected.
- Failed to give a sufficient Sensor Error, Transmitter Error, Signal Loss, or No Readings alert.

94.

Dexcom failed to adequately warn of the above design and manufacturing defects.

95.

The G6 System also failed to adequately warn that the G6 System sometimes failed to give either a System Alert (such as a Signal Loss Alert) or a Glucose Alert (such as an Urgent Low alarm), leaving the user without knowledge that the G6 System had stopped monitoring glucose levels and that the user needed to switch to another blood glucose testing method for diabetes treatment decisions.

96.

Specifically, and without limitation, this warning should have been included in the User Guide warnings on pages 35-36 of Exhibit A.

97.

The failure of the G6 System to alert Michael Tuttle to his hypoglycemia caused him not to recognize or to treat his severe hypoglycemia, which ultimately caused him to die from anoxic brain injury and acute respiratory failure. As such, the G6 System was the proximate cause of the damages suffered by Michael Tuttle. Dexcom is strictly liable for the damages incurred by Plaintiff and Michael Tuttle as a result of the defective product.

## **COUNT TWO – NEGLIGENCE**

98.

Dexcom designs, develops, manufactures, promotes, supplies, distributes,

sells, and instructs in the use of the Dexcom G6 Continuous Glucose Monitoring System (“G6 System”).

99.

Dexcom has a duty to exercise reasonable care to design products that are reasonably safe for intended or foreseeable uses.

100.

Dexcom has a duty to exercise reasonable care to manufacture products that are reasonably safe for intended or foreseeable uses.

101.

The Dexcom G6 System is intended to replace fingerstick blood glucose testing for diabetes treatment decisions.

102.

During the time that Michael Tuttle had his fatal hypoglycemic event, he was using the G6 System according to Dexcom’s Recommended Smart Device Settings.

103.

Data from the Dexcom Daily Report and the Dexcom audit logs show the G6 System stopped detecting Michael’s glucose levels or providing alerts at approximately 10:37 p.m. and did not restart before Michael’s wife found him

unresponsive due to his hypoglycemia.

104.

Dexcom breached its duty to exercise reasonable care in its design and manufacture of the G6 System because Dexcom knew or should have known that the G6 System was not reasonably safe for intended or foreseeable uses because it:

- Failed to prevent clinically significant gaps in sensor data availability that prevented digitally connected devices from achieving their intended use.
- Failed to ensure secure and reliable means of data transmission to provide real-time glucose readings at clinically meaningful time intervals to devices intended to receive the glucose data.
- Failed to ensure that the intended user can use the device safely and obtain the expected glucose measurement accuracy.
- Failed to give a Low alert when the user's glucose level fell below 70 mg/dl.
- Failed to give an Urgent Low Soon alert when the user's glucose level were falling fast and would be 55mg/dl in less than 20 minutes.
- Failed to give an Urgent Low alarm when the user's glucose level fell below 55 mg/dl and to repeat that alarm every 30 minutes.
- Failed to give a Sensor Error alert when a sensor error occurred.

- Failed to give a Transmitter Error alert when the transmitter was not working.
- Failed to give a Signal Loss alert when signal was lost.
- Failed to give a No Readings alert when no readings were detected.
- Failed to give a sufficient Sensor Error, Transmitter Error, Signal Loss, or No Readings alert.

105.

Dexcom negligently failed to adequately warn of the above design and manufacturing defects.

106.

The G6 System also failed to adequately warn that the G6 System sometimes failed to give either a System Alert (such as a Signal Loss Alert) or a Glucose Alert (such as an Urgent Low alarm), leaving the user without knowledge that the G6 System had stopped monitoring glucose levels and that the user needed to switch to another blood glucose testing method for diabetes treatment decisions.

107.

Specifically, and without limitation, this warning should have been included in the User Guide warnings on pages 35-36 of Exhibit A.

108.

The failure of the G6 System to alert Michael Tuttle to his hypoglycemia caused him not to recognize or to treat his severe hypoglycemia, which ultimately caused him to die from anoxic brain injury and acute respiratory failure. As such, the G6 System was the proximate cause of the damages suffered by Michael Tuttle. Dexcom is liable for the damages incurred by Michael Tuttle as a result of its negligence in designing, manufacturing, and warning about the G6 System.

**COUNT THREE – BREACH OF WARRANTY**

109.

Dexcom made express warranties pursuant to O.C.G.A. § 11-2-313.

110.

Michael Tuttle was the original owner of a new Dexcom G6 system which he purchased from Dexcom.

111.

Dexcom included a User Guide for the G6 System contemporaneously with the sale and as part of the sale of the G6 System. See Exhibit A; Dexcom's Supporting Brief, 8.

112.

In the User Guide for the G6 System, Dexcom made affirmations of fact or promises related to the G6 and included descriptions of the G6, which were part of the basis of the sale of the G6, including:

- The Dexcom G6 System is intended to replace fingerstick blood glucose testing for diabetes treatment decisions. Exhibit A, 20.
- Your alarm and important alerts sound and display information even when your volume is low or muted. Specifically, if your smart device is on mute and you have the Always Sound setting turned on (the default setting), only these notifications make a sound:
  - Glucose Alarm/Alerts: Urgent Low, Urgent Low Soon, Low Glucose, High Glucose, Rise Rate, Fall Rate, No Readings Alert. Exhibit A 28, 54.
  - System Alerts: Calibration Required, Calibration, Sensor Expired, Replace Sensor, Transmitter (not working), No Storage Error, App Stopped. Exhibit A 28, 54.
- Signal Loss alert would sound unless the Apple device being used as the receiver was set to low volume, muted, or set to Silent/Do Not Disturb. Exhibit A, 29, 55.

- With G6, there's no need to take fingersticks to calibrate the system or for treatment decisions (as long as your symptoms match your G6 readings). Exhibit A, 38.
- The alarm/alerts features (Chapter 10) keep you aware of your glucose levels. Alarm/alerts notify you when your glucose goes outside your target range, goes too low, or too high, or is rapidly falling or rising. This lets you take action to prevent glucose from going too low or high. Exhibit A, 38.
- Alarm/alerts warn you when you need to take action; for example, when your BG is too high or too low. Exhibit A, 43.
- The Urgent Low Soon Alert notifies you when your G6 reading is predicted to reach 55 mg/dL within 20 minutes. This helps you to determine what the appropriate treatment action will be before your glucose levels drop too low. Exhibit A, 44.
- Always Sound: You can override your phone settings so your alarm/alerts will always sound, even when your phone is on mute/Do Not Disturb. Exhibit A, 51
- Enable Dexcom app notifications so you get alarm/alerts. Exhibit A, 53.
- Dexcom G6™ Continuous Glucose Monitoring System (G6) alarm/alerts can keep you safe from severe lows or highs. Exhibit A, 133.

- When your G6 reading goes from your target range to your alarm/alerts level, your display device tells you with a visual notification, and vibrations or sound, depending on the alarm/alert and your display device. Until you confirm the glucose-related alarm/alert, every 5 minutes you get the alarm/alert screen along with a notification and a vibration. Until you're back in your target range, the alarm/alert information will stay on your home screen. Exhibit A, 135.
- Urgent Low Soon Alert: This alert lets you know you're falling quickly, in fact so quickly that you'll be at or below 55 mg/dL within 20 minutes, no matter where you are now – even if you're in your target range. This gives you time to act before you go too low. Exhibit A, 138.
- You always get your Urgent Low Alarm. Exhibit A, 141.
- Signal Loss Alert: This tells you when you're not getting G6 readings. Initial alert: Vibrates once. Until confirmed: Vibrates and beeps once every 5 minutes. Exhibit A, 145.
- All system alerts also vibrate and beep once. Exhibit A, 145.
- Alarm/alerts require you to confirm them. Exhibit A, 148.
- Due to its medical importance, the alarm is more persistent. Even after the alarm is confirmed, if your G6 readings remain at or below 55 mg/dL, the

Urgent Low Alarm will sound every 30 minutes until G6 readings are above 55 mg/dL. Exhibit A, 148.

- Your Urgent Low Alarm will always repeat, even after confirming, if your glucose levels don't return to your target range. You can't change your Urgent Low Alarm. Exhibit A, 148.
- Is your smart device muted/silenced? To make sure you do not miss a high or low, your alarm/alerts sound anyway. Exception: If your Apple smart device is silenced, you will not get the Signal Loss alert. Exhibit A, 226.
- If display device misses 20 minutes of sensor glucose data (4 readings), the Signal Loss error displays. Exhibit A, 327.
- The G6 System would provide users with System Alerts if the transmitter, sensor, or app stopped working. Exhibit A, 333 – 337.
- The G6 System would provide users Glucose Alerts if a user's glucose fell outside a certain window or changed too rapidly. Exhibit A, 337 – 339.
- The G6 System would provide users with No Data Alerts, including a Signal Loss Alert and a No Readings Alert if the G6 system lost signal or did not take readings. Exhibit A, 339.

113.

At the time of making this warranty, Dexcom knew or should have known

that the G6 System would be used by persons under similar circumstance to those circumstances of Michael Tuttle and that Michael Tuttle was therefore within the class of persons reasonably to be expected to be endangered by breach thereof.

114.

Michael Tuttle relied on Dexcom's affirmations of fact, promises, and descriptions included in the User Guide as shown by his use of the alerts and notifications of the G6 to make treatment decisions.

115.

The G6 System did not perform as expressly warranted by Dexcom because when Michael Tuttle experienced severe hypoglycemia after 10:30 pm. on November 9, 2019, the G6 System failed to provide an alert or alarm to Michael.

116.

Dexcom also made implied warranties pursuant to O.C.G.A. § 11-2-314.

117.

Because Dexcom is a merchant with respect to glucose monitoring systems such as the G6 System, the G6 system must be fit for the ordinary purposes for which such goods are used and conform to the promises or affirmations of fact made on the container or label if any.

118.

As such, the G6 must meet the merchantability requirements of O.C.G.A. § 11-2-314.

119.

“The Dexcom G6 System is intended to replace fingerstick blood glucose testing for diabetes treatment decisions.” This is the ordinary purpose for which the G6 System is used. Exhibit A, 20; Exhibit B, 1; Exhibit C, 2.

120.

The G6 was not merchantable because despite this stated purpose, the G6 System was not fit to replace fingerstick blood glucose testing for diabetes treatment decisions. When Michael Tuttle experienced severe hypoglycemia after 10:30 pm. on November 9, 2019, the G6 System failed to provide an alert or alarm to let Michael know that his glucose levels were dangerously low and were not being monitored.

121.

More generally, the G6 System was not fit to function as a primary glucose monitoring system because when it failed to provide any alerts, as it did here, the user was left with the mistaken impression that their glucose levels were being monitored. This failure could happen late at night, as it did here, when the average

user would be sleeping and absent an alert or alarm, completely unaware of any reason to revert back to fingerstick blood glucose testing until too late.

122.

Additionally, the G6 System was not merchantable because it failed to conform to the promises or affirmations of fact made in its User Guide because when Michael Tuttle experienced severe hypoglycemia after 10:30 pm. on November 9, 2019, the G6 System failed to provide an alert or alarm to Michael.

123.

At the time of making this warranty, Dexcom knew or should have known that the G6 System would be used by persons under similar circumstance to those circumstances of Michael Tuttle and that Michael Tuttle was therefore within the class of persons reasonably to be expected to be endangered by breach thereof.

124.

Dexcom's breach of its express and implied warranties caused Michael Tuttle not to recognize or to treat his severe hypoglycemia, which ultimately caused him to die from anoxic brain injury and acute respiratory failure. As such, Dexcom's warranty breaches were the proximate cause of the damages suffered by Michael Tuttle. Dexcom is liable for the damages incurred by Michael Tuttle as a result of the breach of its warranties.

**COUNT FOUR – WRONGFUL DEATH**

125.

Plaintiff was the wife of Michael Tuttle and is the legal next-of-kin.

126.

Due to the Defendant's strict liability, negligence, and breach of warranty, Defendant is liable to Plaintiffs pursuant to O.C.G.A. § 51-4-2 for the wrongful death of her husband, Michael Tuttle.

**COUNT FIVE – PUNITIVE DAMAGES**

127.

The actions of Dexcom showed willful misconduct, malice, fraud, wantonness, oppression, and that entire want of care which would raise the presumption of conscious indifference to consequences. See O.C.G.A. § 51-12-5.1.

128.

For example, Dexcom knew that the G6 System sometimes failed to give alerts or alarms to users when they experienced hypoglycemia, leaving them unaware of their hypoglycemia and the lack of monitoring.

129.

Among other methods, Dexcom gained this information through MAUDE, social media, diabetic forums, and its own technical support.

130.

Despite recognizing that this failure to give any alert or alarm subjected its users to a severe risk of untreated hypoglycemia, Dexcom failed to timely investigate or report this risk.

131.

Because many of the documents demonstrating Dexcom's knowledge of this and other risks are not publicly available, Plaintiff does not yet know the extent of Dexcom's punitive behavior.

WHEREFORE, Plaintiff prays judgment as follows:

1. That Plaintiff recover for special damages including but not limited to medical expenses and funeral expenses in an amount to be proven at trial.
2. That Plaintiff recover for Michael Tuttle's pain and suffering and general damages in an amount to be proven at trial;
3. That Plaintiff recover punitive damages in an amount to be determined at trial;

4. That Plaintiff recover the full value of the life of Michael Tuttle under the wrongful death statute;
5. That all costs of this suit be taxed against Defendant; and

For such other and further relief as the Court deems just and proper.

This 8th day of January, 2021.

Respectfully submitted,

/s/ NATALIE S. WOODWARD

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**CERTIFICATE OF SERVICE**

I hereby certify that on this date I electronically filed the First Amended Complaint using the CM/ECF system which will automatically send e-mail notification of such filing to the following attorneys of record:

Paul Weathington, Attorney for Defendant

Zach H. Fuller, Attorney for Defendant

Paul J. Cosgrove (pro hac vice forthcoming), Attorney for Defendant

Mary Lynn Tate (pro hac vice forthcoming), Attorney for Defendant

Georgia Hatzis (pro hac vice forthcoming), Attorney for Defendant

This 8<sup>th</sup> day of January, 2021.

/s/ NATALIE S. WOODWARD

Natalie S. Woodward

Ga. Bar No. 773827

*Attorney for Plaintiff*